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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467

28008 7590 07/13/2006

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,445	BARCLAY ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-23 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/14/06 has been entered.

Response to Amendment

The rejection of claim 11 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claim 9-23 under 35 U.S.C. 112 1st paragraph (written description) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 9-23 under 35 U.S.C. 101/112 1st paragraph is maintained for reasons set forth of the record mailed on 12/14/05 and further discussed below.

Claims 15, 20 and 22 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC § 101

Claims 9-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility.

Claims 9-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to this rejection, Applicants argue that the claimed invention is useful to treat multiple sclerosis, which is a credible, substantial and specific utility. Applicants assert that multiple sclerosis is a disease state that can be treated by modulating OX2R activity, thus down-regulates mast cell function. Further, Applicants assert that the instant specification teaches a link between MS and OX2R because it teaches 1) cells of myeloid lineage were thought to play a role in the development of MS; 2) OX2R was known to be expressed on cells of the myeloid lineage; 3) OX2R was known to play a role in signal transduction, and 4) altering the interaction of OX2R and OX2 impacts mast cell activity. Applicants cited references to support each of the above statement. Applicants thus conclude that the claimed invention has patentable utility.

The above arguments have been fully considered but deemed unpersuasive. As discussed in the previous office action, the examiner maintains the position that using claimed antibody or fragment for treating diseases such as multiple sclerosis is not a credible, substantial and specific use. Although CD200 is known as a cell surface antigen identified in some specific cell type

such as mast cells, that are involved in inflammatory conditions, multiple sclerosis, rheumatoid arthritis, and autoimmune disease, the specification does not teach which specific disease is the result from the this particular CD200R. In other words, the specification does not teach which specific signal transduction pathway (the CD200R is involved in) in any specific cell type that leads to a specific disease, multiple sclerosis. The assertion that CD200R is involved in multiple sclerosis based on the involvement of cells, for example, macrophages and dendritic cells, which are known to be involved in said disease. However, there is no teaching whether the involvement of such cells in those diseases is result from the expression of said CD200 antigen. Applicants are reminded that expression of a protein in certain cell type does not mean that said protein is responsible for all the activity of such cell type. Thus, the disclosure provided in the specification only establishes the association of mast cells and multiple sclerosis, which does not provide a specific association between said diseases and CD200R. The examiner does not dispute 1) cells of myeloid lineage were thought to play a role in the development of MS; 2) OX2R was known to be expressed on cells of the myeloid lineage; 3) OX2R was known to play a role in signal transduction, and 4) altering the interaction of OX2R and OX2 impacts mast cell activity. However, based on the above information, a skilled artisan would not be able to conclude that the claimed OX2R antibody can be used to treat multiple sclerosis because the specification does not teach how to treat said disease using the claimed antibody. In fact, the specification teaches against such utility because a human-IgG mouse OX2RH1 fusion protein that binds to OX2 accelerated the onset of EAE in a mouse model. The fact this fusion protein which disrupts the interaction of OX2 and OX2R would result in disease acceleration indicate that said antibody cannot be used to treat disease. Therefore, using the claimed antibody and the

fragment to treat multiple sclerosis is not a credible, substantial and specific utility. This rejection is maintained.

In response to the 112 1st rejection, Applicants argue that the claimed invention is enabled because they have utility. Applicants further assert that the amendment renders the claimed invention enabled because they are directed to antibodies that bind to SEQ ID NO:20.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed invention is set forth in the previous office action. In response to the argument of using the claimed antibody for MS, Applicants are reminded that the instant specification fails to teach how to use said antibody for such treatment. The specification does not teach or provide any working example that any therapeutic effect is seen in patients or animal model when the antibody is administered. In fact, the teaching of the specification is against such use (for reasons discussed above). The prior art does not teach how to use an OX2R antibody to treat MS. Without teaching from the specification and lack of such information from prior art, one of skill in the art will have to engage in undue experimentation to practice use the claimed invention to treat multiple sclerosis. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 20 and 22 recite the limitation "or a fragment thereof" in line 3. In the parent claim 9, the fragment of SEQ ID NO:20 is deleted. There is insufficient antecedent basis for this limitation in the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER